REMARKS

Claims 22-29, 34-41, 46 and 47 are pending in the application.

I. THE WRITTEN DESCRIPTION REJECTION IS TRAVERSED

The Office Action of 20 February 2007 rejects claims 22-29, 34-41, 46 and 47 because the specification allegedly fails to describe the describe the invention "in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Office Action of 20 February 2007, *page 2*. Specifically, the Office Action states that the "specification does not disclose a single example of a recombinant MHC comprising a class II heavy chain HLA monomer, a class II beta-2microglobulin HLA monomer and a folding peptide." *Office Action of 20 February 2007*, page 2-3. The presently claimed invention, however, is drawn towards methods of depleting anti-MHC antibodies in a sample using recombinant MHC molecules, but is not directed to the recombinant MHC molecules themselves. In other words, the present claims do not claim recombinant MHC molecules *per se*, but instead they claim methods of using these recombinant MHC molecules to deplete anti-MHC antibodies.

Applicants respectfully disagree with the Office Action and assert that the specification fully describes the claimed invention. In particular, the specification states that

> [t]he invention does however also extend to class II MHC molecules. Especially preferably the MHC molecules are in monomeric form. Said monomeric form however refers to the minimum number of components necessary to display one or more epitopes corresponding to an epitope of a naturally occurring MHC allele, e.g. a heavy chain, β-microglobulin and an associated peptide. However, for class II MHC molecules, less components may be necessary to form the epitope. Therefore, it may not be necessary to include the associated peptide, for example, for class II molecules.

United States Pre-Grant Publication 2004/0191245, ¶0037. Thus, the specification provides explicit support for "a recombinant MHC comprising a class II heavy chain HLA monomer, a class II beta-2microglobulin HLA monomer and a folding peptide."

Furthermore, it appears that the Office Action's written description rejection is premised on the alleged lack of working examples in the specification. Applicants assert that the lack of working examples is not the standard for satisfying the written description requirement of 35 U.S.C. §112, first paragraph. In fact, "[a] claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language." *LizardTech, Inc. v. earth Resource mapping, PTY, Inc.,* 424 F.3d. 1336, 1345 (Fed. Cir. 2005) (citations omitted). *See Univ. of Rochester v. G.D. Searle & Co.,* 358 F.3d 916, 926 (Fed. Cir. 2004) ("We of course do not mean to suggest that the written description requirement can be satisfied only by providing a description of an actual reduction to practice.")

Recently, the Court of Appeals for the Federal Circuit upheld a decision of the Board of Patent Appeals and Interferences ("the Board") and unambiguously stated in *Falkner v. Inglis,* 448 F.3d 1357 (Fed. Cir. 2006), that working examples are not necessary to provide adequate written description support. The facts behind *Falkner* are so similar to the present application that the Board's and Federal Circuit's decisions are instructive. The technology at issue was a poxvirus vaccine that comprises "a DNA polynucleotide encoding an antigen … ." Falkner challenged the validity of the pending Inglis claims under the enablement and written description requirements of 35 U.S.C. §112, first paragraph, because the Inglis applications did not contain any working examples of the claimed vaccine and thus contained no evidence of a reduction to practice. In reviewing the Board's decision, the Federal Circuit noted that "the Inglis applications described vaccine vectors in general, and then focused on the subgenus of herpesviruses, …." *Falkner v. Inglis*, at 1364. Furthermore, the Federal Circuit noted that "the Inglis applications do not describe any actual reduction to practice of a poxvirus vaccine." In spite of the lack of working examples, the Federal Circuit affirmed the Board's holding that "an actual reduction to practice is not required for written description." *Falkner v. Inglis*, at 1366. The Federal Circuit then emphasized that "to the extent that written description requires a showing of possession of the invention," it is conception, not reduction to practice is the invention. *Falkner v. Inglis*, at 1367 (internal quotations omitted) (citations omitted).

Here, the specification clearly and explicitly states that the inventors contemplated the use of class II MHC monomers, class II β-microglobulin monomers and a folding peptide. *See* United States Pre-Grant Publication 2004/0191245, ¶0037. While the specification does not necessarily provide working examples of the present claims, the explicit support provides a clear indication that the inventors had in their possession the complete concept of an invention that uses class II MHC monomers, class II β-microglobulin monomers and a folding peptide. Accordingly, the explicit support in the specification is ample evidence that the specification provides adequate written description of the present claims.

Applicants assert that the specification fully describes the claimed invention. Applicants respectfully request reconsideration and withdrawal of the written description rejection.

II. THE ENABLEMENT REJECTION IS TRAVERSED

The Office Action of 20 February 2007 rejects claims 22-29, 34-41, 46 and 47 because the specification allegedly fails to describe the invention "in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." *Office Action of 20 February 2007*, page 3. Applicants respectfully disagree.

As an initial matter, it is noteworthy that a previous Office Action in this same application establishes, without limitation to either class I or class II monomers, that the specification is "enabling for recombinant MHC monomers" *See Office Action of 6 July 2006,* page 4 (emphasis added). The rejection at that time was focused on the lack of enablement for all recombinant MHC molecules. Now, the present Office Action is rejecting claims towards MHC monomers, even though the previous Office Action established that the specification fully enabled MHC monomers, without caveat.

Applicants respectfully disagree with the Office Action and assert that the specification, when viewed in light of the states of the art at the time of filing, fully enables the scope of the claimed invention. Specifically, the Office Action states that "[t]he specification fails to provide any working examples of recombinant MHC comprising a class II heavy chain HLA monomer, a class II beta-2-microglobulin HLA monomer and a folding peptide." *Office Action of 20*

February 2007, page 4. While the presence or absence of working examples may be helpful to demonstrate that a specification enables specific claims, this factor is not dispositive.

Again, *Falkner v. Inglis* is instructive when examining the present application to determine of the claims are enabled. In addition to affirming written description, the Federal Circuit also affirmed the Board's holding that the Inglis applications provided enablement for the pending claims, even though the Inglis applications did not contain a single working example of an embodiment of the claims. In reviewing the specification for the case at bar, the Federal Circuit noted, among other factors, the state of the art at the time of filing.

With regards to the state of the art at the time of filing, the Office Action states that "the synthesis of class II MHC monomers at the time of the invention was not well known in the art." *Office Action of 20 February 2007*, page 4-5. Yet, the Office Action of 6 July 2006 cites United States Patent No. 6,232,445 as disclosing "recombinant MHC class II molecules." Thus, by the Office's own admission, recombinant MHC class II molecules were part of the state of the art at the time of filing.

The Office Action establishes that the specification "provides guidance on recombinant MHC class I molecules." *Office Action of 20 February 2007*, page 4. And the same recombinant techniques used to generate recombinant MHC class I monomers of the present application can certainly be used to generate MHC class II monomers. Because the same well-known techniques can be used to generate recombinant MHC class II molecules, it is therefore not necessary that the specification recite what is well-known in the art. Indeed, "[a] patent need not teach, and preferably omits, what is well known in the art." *Spectra-Physics, Inc. v. Coherent, Inc.,* 827 F.2d 1524, 1534 (Fed. Cir. 1987).

The Office Action provides no evidence as to why well-known recombinant techniques could not be used to generate MHC class II monomers. Instead, the Office Action states that "MHC class I and MHC class II have completely different structures and different functions." *Office Action of 20 February 2007*, page 4. The structure and function of MHC class I and class II molecules, however, are entirely irrelevant to the claims at hand. Rather, the present claims are directed to using recombinant MHC class II monomers to deplete antibodies from a sample.

Because well-known techniques could be used to generate the recombinant MHC class II monomers, Applicants assert that the specification fully enables the presently claimed invention.

The Office Action also states that "one of ordinary skill in the art would have a low level of predictability in making MHC class II monomers that present a unique epitope of a naturally occurring MHC allele … ." *Office Action of 20 February 2007*, page 5. The claims, however, do not recite such limitations to "unique epitopes." While recombinant MHC molecules are elements of the claims, and therefore necessary for performance of the methods, there is no requirement that the recombinant MHC molecules present "unique epitopes" of MHC molecules. To the contrary, the claims and specification state that the recombinant MHC molecules must have a known identity and that the depleted antibodies be specific for naturally occurring MHC alleles. Indeed, the specification states that "[t]hese recombinant MAC or MHC-type monomers, functioning as anti-MHC antibody antigens, have the advantage that the identity of the MHC is known." United States Pregrant Publication No. 2004/0191245 A1, ¶0016 (emphasis added). Furthermore, the specification indicates that, to deplete anti-MHC antibodies, the recombinant MHC molecules should maintain "not only residues at the epitopic site, but also key skeletal residues to achieve correct folding of the MHC molecule to form the epitopic site." United States Pregrant Publication No. 2003/0017447 A1, ¶0025. Thus, the specification indicates that, contrary to the Examiner's interpretation of the claims, the recombinant MHC molecules should be produced to preserve epitopic sites, rather than to generate "unique epitopes."

This identical issue was recently discussed in the parent application to the present application, United States Serial No. 09/809,029. After a pre-appeal brief conference request was filed, the enablement rejection, which was directed to lack of enablement of recombinant MHC molecules for both class I and class II, was removed and the specification was deemed to fully enable the claims. Here, the claims comprise elements of MHC class II monomers. Surely, if the parent specification, with a nearly identical disclosure, enables recombinant MHC molecules, then the present application fully enables class II MHC monomers, which are a species of MHC molecules.

Accordingly, the specification fully describes the claimed invention. Applicants respectfully request reconsideration and withdrawal of the enablement rejection.

III. THE INDEFINITENESS REJECTION IS TRAVERSED

The Office Action of 20 February 2007 rejects claims 22-29, 34-41, 46 and 47 because the claims are allegedly "indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." *Office Action of 20 February 2007,* page 5.

Specifically, the Office Action states that "the recitation 'recombinant MHC-type molecules' [in claim 22] is vague and indefinite." *Office Action of 20 February 2007,* page 6. Applicants respectfully disagree. The specification states that "HLA-type molecules" are molecules that "exhibit[] the properties of an HLA molecule ("HLA-type") … ." *United States Pre-grant Publication No. 2004/0191245*, ¶37. As one of skill in the art is well aware, and as the specification clearly points out, "MHC molecules in humans[]are referred to as Human Leukocyte Antigen (HLA) molecules." *United States Pre-grant Publication No. 2004/0191245*, ¶0003. Thus, ever a reader with less than ordinary skill in the art would be able to understand that an MHC-type molecule is a molecule that exhibits the properties of an MHC-molecule.

The Office Action also states that "the recitation 'folding peptide' [in claim 22] is vague and indefinite." *Office Action of 20 February 2007,* page 6. Applicants respectfully disagree. As the Office is well aware, claim terms are to be given their plain and ordinary meaning. Furthermore, the specification is replete with examples of monomers that were folded around peptides. Indeed, paragraph 0074 of the published application states that "complexes [were] made up of … monomers refolded around HIV- or EBV-derived peptides." *United States Pre-grant Publication No. 2004/0191245*, ¶0074. Further, Table 1 lists peptides that were used to fold monomers. *See United States Pre-grant Publication No. 2004/0191245*, ¶0078 ("The monomers used had been folded with the peptides listed in table 1.") Thus, the specification is clear as to what is intended by the term "folding peptide."

The Office Action also states that "the recitation 'recombinant HLA-type molecules' [in claim 36] is vague and indefinite." *Office Action of 20 February 2007,* page 6. Applicants respectfully disagree. The specification clearly states that "HLA-type molecules" are molecules that "exhibit[] the properties of an HLA molecule ("HLA-type") … ." *United States Pre-grant Publication No. 2004/0191245,* ¶37.

Accordingly, the claims clearly define the metes and bounds of the invention in light of the teachings of the specification. Applicants respectfully request reconsideration and withdrawal of the indefiniteness rejection.

IV. CONCLUSION

Applicants have not amended the claims. In view of the above discussion, Applicants respectfully request reconsideration and withdrawal of the claim rejections. Applicants assert that allowance of this application is in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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